JUN 3 0 2004 K0 33984

ATTACHMENT 6 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert, Director of Regulatory Affairs

2. **Name of the Device**

Trade Name: ITI Dental Implant System®
Common Name: Dental Implant
Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

ITI Dental Implant System (K971578, K983742, K984104, K003271, K010291, K012757 and K030007)
Friadent CELLplus implants (K031674, K032158, K032284)

4. **Description of the Device**

The Straumann solid screw dental implants are of various diameters and lengths with an anchorage surface that is grit blasted and acid etched. This surface has been modified for faster osseointegration and secondary stability. The dental implants are composed of Grade 4 titanium, cold worked. The neck of the implant is a smooth machined surface to allow for the attachment of epithelial tissue. Straumann implants are available in a range of endosseous diameters (3.3 to 4.8 mm) and lengths. No changes to overall implant design or dimensions were made.

5. **Intended Use of the Device**

For immediate or delayed placement in the maxillary and/or mandibular arches to support crowns, bridges and overdentures in edentulous or partially edentulous patients.

6. **Basis for Substantial Equivalence**

The subject dental implants are identical to the currently marketed ITI dental implants in intended use, material and design. The subject SLActive dental implants have the same indications for use as the currently marketed ITI dental implants. The subject device is the same as the currently marketed ITI dental implants with a modified surface. This surface promotes faster osseointegration. Increased bone to implant contact and earlier secondary stability with the modified surface compared to the SLA surface was demonstrated at early healing periods of 2-4 weeks in animal studies. This improved bone anchorage

provides increased implant stability during the important early treatment periods in immediate and early loading procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Institut Straumann AG
C/O Ms. Linda Jalbert
Director, Regulatory Affairs
Straumann USA
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K033984
Trade/Device Name: ITI Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: April 13, 2004
Received: April 14, 2004

Dear Ms. Jalbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033984

Device Name: ITI Dental Implant System

Indications for Use: The ITI Dental System implants are for single-stage or two-stage surgical procedures. The ITI Dental System implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used in immediately loaded cases.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033984

Prescription Use ___x___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)